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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,501

Applicant(s)

PAUL ET AL.

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claims 30 and 31 remain pending and under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant has pointed out that the specification at page 24 defines "porcine reproductive and respiratory syndrome virus" and that page 28, line 22-page 29, line 10, defines an Iowa strain.

These arguments have been considered but not found persuasive. The specification at page 28, line 22-page 29, line 10 provides a list of five characteristics, denominated (a)-(e), and states that "preferably, the Iowa strain is characterized by at least two of the above characteristics (a)-(e)." This indicates what characteristics are preferred in an Iowa strain but does not clarify what polynucleotide or polynucleotide composition Applicant intends to claim. Applicant has not addressed the fact that Figs. 8, 10, 17, 18, 21, e.g., of the instant specification indicate that there are several stretches of at least 10 nucleotides within the sequence of the Lelystad virus that are identical to corresponding sequences within viruses disclosed as being "Iowa strain" viruses. It remains unclear what primer of 10-50 nucleotides Applicant is claiming, since certain primers encompassed by claims 30 and 31 would hybridize equally well with Lelystad virus, e.g.

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Since claims 30 and 31 recite features not disclosed in parent application 08/131,625 or in 07/969,071, they receive the effective filing date of 08/30/1994, i.e., September 1, 1994.

Applicant has argued that US Patent 5,695,766 which issued from parent application 08/131,625, filed October 5, 1993, and US application 07/969,071, filed October 30, 1992, both disclose diagnostic kits; that 07/969,071 discloses the Iowa strain virus ISU-12; and that the '766 patent discloses primers of 10-50 nucleotides in length.

These remarks have been considered but not found persuasive. The parent applications at the locations cited do not disclose or provide support for kits comprising primers with the specific length limitations of 10-50 nucleotides that hybridize under the specific conditions recited in claim 30 nor do they disclose the use of an intercalating dye as recited in claim 31.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor, and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort et al., WO92/21375, published December 10, 1992, and cited by Applicant on PTO 1449 for reasons of record in the previous Office action.

Applicant has argued that Wensvoort et al. discloses the Lelystad virus which does not fit the definition of "Iowa strain" as provided by the instant specification, and that it would not have been obvious to select a primer of 10-50 nucleotides in length that would hybridize to an Iowa strain.

This has been considered but not found persuasive. Since the genomes of Iowa strain PRRSV and Lelystad virus share sequence identity over stretches of 10 nucleotides or more, and since the claims are unclear as discussed above, primers of 10-50 nucleotides that hybridize to Iowa strain genome at 25-75°C are deemed obvious over the disclosure of Wensvoort et al. of the Lelystad

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sequence and the suggestion to select appropriate primers for polymerase chain reaction, for example, and to use conventional detection means for detecting the nucleic acids that result. Because disclosed Iowa strain or strains have stretches of 10 nucleotides or more that are identical to nucleotide sequences of Lelystad virus, the claims are obvious over compositions comprising primers as taught by Wensvoort et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 1-29 and 32-38 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone

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number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
January 23, 2003